

# The effectiveness of digital imaging and remote expert wound consultation on healing rates in chronic lower leg ulcers in the Kimberley region of Western Australia

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## Abstract

The incidence of chronic lower limb ulcers in remote regions of Australia is high and results in significant morbidity, decreased quality of life and high cost. These wounds present challenges to clinicians due to their complex nature, high levels of comorbidity and the difficulty of gaining expert wound consultation due to distance.

A 12 month prospective randomised controlled trial was conducted at four sites in the Kimberley region of Western Australia (WA). The aim was to examine the effect on clinical outcomes and costs of providing remote expert wound consultation using the Alfred/Medseed Wound Imaging System (AMWIS) for patients with chronic leg and foot ulcers. All patients (n=93) had sequential wound assessments conducted using AMWIS at each clinic attendance. Control patients (n=43) received standard wound care, whereas intervention group patients (n=50) had their digital records transmitted to Perth every 2 weeks for remote review by a wound care consultant; these were then returned to their treating clinician with wound management advice.

Results indicate that intervention group patients had a positive healing rate of 6.8% per week, whereas controls had a negative rate of -4.9% per week ( $p=0.012$ ). There were six amputations in the control group and one in the intervention group. The estimated treatment cost difference between the groups at 12 months was \$191,935 lower in the intervention group. We believe that our findings provide early evidence of the clinical and cost effectiveness of remote expert wound consultation using a digital wound imaging system in geographically remote regions.

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## Introduction and background

Chronic wounds of the lower extremity (leg ulcers) are a major source of morbidity and decreased quality of life in the Australian population. Indigenous communities in particular have a very high incidence of chronic lower leg ulcers; this is in part due to the high incidence of diabetes within these communities, estimated to be 7-8 times higher than non-indigenous Australians<sup>1</sup>. Diabetes is a major aetiological factor in the development of chronic leg and foot ulcers<sup>2</sup>; these ulcers can persist for months or even years. They have a significant negative impact on the individual's quality of life, are expensive to treat, and can lead to amputation of the affected limb<sup>3</sup>.

The remote Kimberley region of Western Australia (WA) is characterised by a large land mass and a widely dispersed but relatively small population of approximately 33,000<sup>4</sup>. Forty two percent of this population is Aboriginal. This group generally experience poor health status; the incidence of hospitalisation for diabetes in the Kimberley Aboriginal population was reported as 10-16 times that for the rest of WA and the death rate from diabetes in 1997 was the highest in the nation, at four times the Australian rate<sup>5</sup> (Figure 1).

With such high rates of diabetes in this population, the sequelae of vascular disease is correspondingly high, as is the incidence of lower leg ulceration. A review of inpatient

episodes for diagnosis related groups (DRGs) associated with lower leg ulceration treated by the Kimberley Health Service between 1997 and 2003 reveals that there were a total of 473 admissions<sup>4</sup>. Effective treatment of chronic lower leg ulcers of any aetiology is dependent on the appropriate management of the underlying cause. However, it is also significantly influenced by the wound care knowledge level of the treating clinician, accurate assessment and documentation and, where necessary, consultation with wound care experts<sup>6</sup>.

The Kimberley region presents wound care clinicians with additional challenges due to local factors such as the mobility of the population, the difficulty and cost of obtaining expert wound consultation, availability of advanced documentation systems, high staff turnover and geographical isolation.

Telemedicine systems have been suggested as potentially offering benefits to remote communities because of their capacity to provide rapid communication for consultation, minimise social disruption to patients and their families



**Figure 1.** Kimberley patient with diabetic neuropathic foot ulcer complicated by Hansen's disease.

and reduce health care costs<sup>4</sup>. Telemedicine wound care systems such as the Alfred/Medseed Wound Imaging System (AMWIS)<sup>7</sup> are increasingly being used in the hospital sector for the management of acute, complex and chronic wounds due to their advantages over existing methods<sup>8,9</sup>. However, to date, we are not aware of any studies reported in the literature that have specifically investigated the clinical and cost effectiveness of using digital wound imaging systems combined with expert consultation in remote locations. Consequently, the aim of this study was to investigate the clinical effectiveness of using the AMWIS system, combined with remote expert wound consultation on the healing rates in chronic leg and foot ulcers in the Kimberley region.

## Methods

### Design

A 12 month prospective randomised controlled trial was conducted at four sites in the Kimberley region of Western Australia (Broome, Derby, Wyndham and Kununurra) between October 2002 and October 2003. The unit of randomisation was the clinical site; this was in order to avoid the potential for confounding the results due to changes in clinician knowledge level stemming from consultation with the wound care expert. All sites were provided with the current version of the AMWIS software and a Kodak digital camera.

Control group subjects received standard wound care as determined by the local wound care clinician and had their wound photographed and measured at each clinic attendance. Intervention group subjects also had their wound photographed and measured at each clinic attendance;

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however, these images and measurements were electronically transferred every 2 weeks to a wound care consultant (KC) located in Perth.

### Hypothesis

The hypothesis was that intervention sites will have improved wound healing rates in chronic lower leg and foot ulcers and will have lower wound care costs than the control sites.

### End points

- The healing rate was expressed as the percentage change in wound size divided by the number of weeks since enrolment in the trial.
- The clinical cost of wound treatment was considered to be the cost between admission and discharge from trial.

### Subjects & setting

All patients meeting the inclusion criteria and giving informed consent at Broome, Derby, Kununurra and Wyndham hospitals were eligible for enrolment in the study. Patients predominantly had venous, arterial, mixed or diabetic neuropathic ulcers of the lower extremity and were being treated as outpatients at the respective hospitals. We calculated that to detect a clinically meaningful effect size of 12% in the healing rate of wounds with a power of 0.8 and significance level set at 0.05 would require two groups of at least 42 patients each. Prior to commencement of data collection, approval was granted by the Human Research Ethics Committee of The Alfred Hospital and the Western Australian Aboriginal Health Information and Ethics Committee in 2002. Data collection commenced in October 2002 and was completed in October 2003.

### Inclusion criteria

- Documented diagnosis of chronic ulcer of the lower extremity.
- Treated as a wound care outpatient at one of the trial site hospitals.
- Informed consent.

### Exclusion criteria

- Under 18 years of age.
- Disorientation or mental impairment.
- Unstable medical comorbidity.

### Wound measurement

The AMWIS V1 was used to measure and document all wounds according to published methods<sup>7</sup>. All clinical staff involved in the trial were educated by one of the study team (NS) in the use of the AMWIS system and in the process of digital photography. All wounds were photographed, measured and assessed at each clinic attendance by the local wound care nurse. Wound images were recorded using a Kodak DC 440 digital camera. Healing rates were calculated by determining the percentage decrease in surface area calculated in mm<sup>2</sup> between first visit and the discharge visit divided by the total number of weeks treated<sup>10</sup>. This healing rate calculation method was chosen for the study in preference to a per visit healing rate because it is less affected by short term variation in healing that may occur between visits<sup>11</sup>.

### Remote consultation intervention

Wound care nurses at the two intervention sites used the AMWIS remote consultation function to transmit patient files in encrypted form to the wound care consultant every 2 weeks for the duration of the patients' care. The consultant reviewed the wound progress depicted in the electronic AMWIS file of each patient and then transferred the file back to the originating site with comments on the management of the wound entered into the AMWIS 'consultant advice' screen. Below is an example of the AMWIS measurement screens and associated wound management advice provided for one of the intervention group patients with a diabetic neuropathic foot ulcer (Figures 2-4). The consultant also often telephoned the local clinicians to discuss the images, progress of the wound and management options.

### Clinical costing model

The model used to estimate clinical costs was based on international data on the cost of treating a chronic leg ulcer<sup>12, 13</sup> that indicates that the average cost to treat a chronic leg ulcer is A\$27,493 per annum. Using healing rate data that suggests that 83% of chronic wounds heal within 24 weeks<sup>14</sup>, we derived a healing cost per chronic wound of at least \$13,746 after adjusting for cost increases since 2000. Based on this model, overall healing rate costs were allocated thus; 80% of patients were costed at \$13,746 and 20% were costed at \$27,493. These costs were then adjusted based on the actual healing rates for each group. It should be noted that actual costs for individual subjects were not available from the trial sites, therefore we chose to estimate the total group costs for the study.

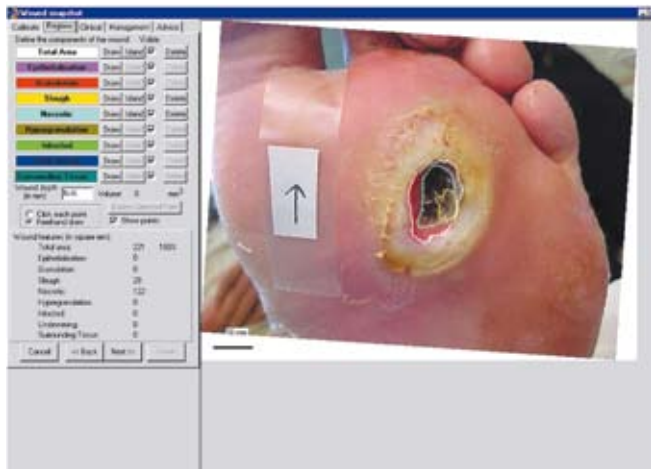


Figure 2. AMWIS information as at 4 March 2003.

"...this chap has multiple comorbidities that will compromise healing. He obviously has small vessel disease and peripheral neuropathy. All you can do to promote better health i.e. diet and diabetes management is important. However, the principal wound management will be to off-load the pressure on the plantar surface and infection control. Once again we need a good orthotic sandal i.e. a Darco shoe with sufficient off-loading.

He would benefit from Iodosorb paste as it will debride and maintain a bacterial balance. Also it would be easy for him to use. A foam secondary dressing would give added pressure relief and protection. I am going to talk to a podiatrist down here to arrange to get you some foot moulds. The idea is to get a foot impression so that we could get temporary off-loading Darco footwear".

Consultant costs are calculated at \$40 per consultation for intervention group patients. Transport costs to Perth were \$1330 per commercial return flight from Broome and \$1980 from Kununurra and approx \$12,000 per Royal Flying Doctor Service (RFDS) one way flight. Flight costs were only included for patients within the study who went on to amputation in Perth during the study. Patients that required RFDS transport from the Kimberley to Perth for amputation due to the severity of their disease and or comorbidity were costed on the basis of DRG IO7Z *Below knee amputation for vascular disease with comorbidity* at \$18,560 per episode.

To enable a balanced comparison between the two groups, the above costing model was applied to 43 patients per group due to the larger number of patients in the intervention group (50 vs 43).

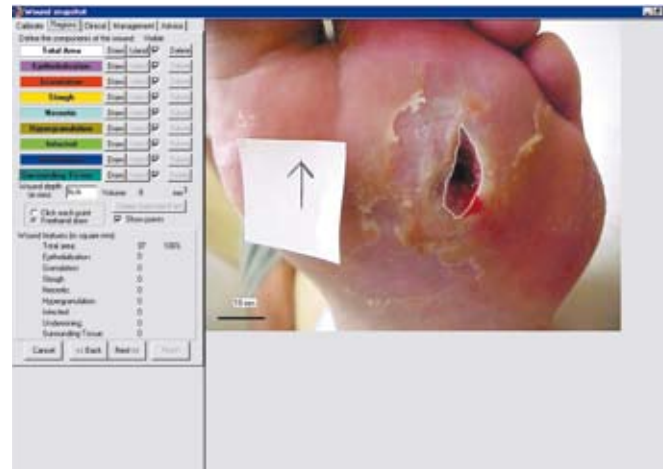


Figure 3. AMWIS information as at 25 March 2003.

"... it was a good thing that he was commenced on OABs. Diabetics with small vessel disease and neuropathy have reduced erythema and sensation and, as these are two of the signs and symptoms of infection, it is frequently missed or not recognised as being significant. So one looks for other signs such as deep sensation, oedema or exudate. The wound looks slightly smaller though. Removal of the surrounding callus is important".



Figure 4. AMWIS information as at 25 May 2003, 2 weeks prior to discharge.

## Analytical procedures

Descriptive statistics were calculated for all subjects. Differences in healing rates between the groups were compared with t tests for independent samples and linear regression was calculated to determine the significance of the differences in healing rates between the groups after adjustment for age and gender. In all cases, significance level was set at 0.05 and all statistical tests were carried out with SPSS V11.



## Funding

The study was funded through a research grant from the Western Australian Department of Health, Telehealth Development Unit.

## Results

### Demographics and wound type

Table 1 reveals that control group subjects were younger than intervention subjects and that there was a greater number of males in the control group. There were also less leg wounds in the control group, but identical numbers of foot wounds between the groups.

**Table 1. Subject demography.**

	Intervention	Control
n	50	43
Age (Mean)	63.5	49.5
Sex (M/F)	24/26	27/16
Wound site		
• Leg	21	14
• Foot	29	29

**Table 2. Ulcer types.**

Ulcer aetiology	Intervention n (%)	Control n (%)
Venous	7 (7.5)	1 (1.0)
Arterial	1 (1.0)	2 (2.0)
Mixed	1 (1.0)	4 (4.0)
Diabetic	25 (27.0)	11 (12.0)
Traumatic	6 (6.5)	12 (13.0)
Surgical	5 (5.5)	0 (0.0)
Pressure	3 (3.0)	11 (12.0)
Burn	2 (2.0)	2 (2.0)
Total	50 (53.5)	43 (46.0)

NB. Wound aetiology was recorded directly from the clinical notes and may not represent the actual wound pathology.

Of note in the aetiology of the chronic ulcers found in the study was the very high incidence of diabetic ulcers in the intervention group (Table 2).

### Clinical outcomes

The mean healing rate difference between the groups was 11.7%; that is intervention group patients (n=50) healed at 6.8% per week, whereas control group patients (n=43) healed at -4.9% per week. This finding was statistically significant at  $p=0.012$ . There were a total of six amputations in the control group and one in the intervention group. Two deaths occurred in the control group during the course of the study (Table 3).

**Table 3. Healing rates.**

Intervention	Control	t	p
6.8%	-4.90	2.57	0.012

**Table 4. Regression analysis.**

Variable	Beta	t	p
Group	-0.310	-2.54	0.013
Age	0.018	0.142	0.888
Sex	-0.202	-1.73	0.080

**Table 5. Cost differences between the groups \*.**

Cost item	Intervention (n=43)	Control (n=43)
Treatment	\$631,026	\$714,801
Amputation	(1) \$18,560	(6) \$111,360
Transport	0	\$36,000
Consultation	\$20,640	\$0
Total	\$670,226	\$862,161

\*Note that 43 subjects per group were used in the costing analysis to eliminate the effect of the larger group of intervention patients.

When age and sex were explored as contributing variables to the healing rates by regression analysis (Table 4), it was found that group membership accounted for the greatest variability in the data. Therefore we conclude that sex and age did not significantly contribute to the differences in healing rates between the groups.

### Clinical costs

There were a total of seven below knee amputations during the course of the study; one in the intervention group and six in the control group. The higher cost in the control group for travel was associated with the severity of comorbidities of three of the control group patients, which required transportation to Perth for surgery. The total cost savings in the intervention group compared to the control group costs was \$191,935. It should be noted that this analysis includes no costs for ongoing management and support for patients who have undergone amputation (Table 5).

### Discussion

The findings of the study demonstrated significant differences in healing rates between the groups, more favourable clinical outcomes and reduced costs in the intervention group compared to controls. The findings on the positive healing rate in intervention group subjects were independent of age and gender, suggesting that group membership accounted for the greatest degree of variability in the groups.

We had difficulty obtaining laboratory results for HbA1c levels for all diabetic patients in the study. These missing data make interpretation of wound care clinical outcome difficult in the diabetic sub-group as there may be an association between delayed healing and poor diabetic control. The practice of not performing regular Hb1Ac measurement in diabetic patients is understood to be a local issue, which is influenced by cultural and pragmatic considerations in a mobile patient population. As a consequence, the results should be interpreted with a degree of caution. A further limitation in the study was the lack of data relating to the degree of compliance with dressings of patients in both groups. Compliance may be an important factor and should therefore be considered in future work in this area.

Amputation rates were much higher in controls than in intervention subjects; however, due to the fact that all subjects undergoing amputation during the study were

diabetic, combined with the lack of HbA1c data in this group, makes direct comparison to diabetic intervention group subjects difficult. The fact that there were also two deaths in the control group and none in the intervention group suggests that controls may have had a higher disease and/or comorbidity severity level than intervention patients.

Obviously healing rates have a direct impact on clinical costs for patients with chronic wounds. Our findings in relation to costs have demonstrated a relatively large difference between the groups. The majority of the higher cost in controls was related to amputation and transport costs; however, excluding surgical and transport cost still produced a saving of \$83,774 in the intervention group due to reduced length of treatment. No calculation was undertaken for the ongoing cost of the care of individuals following amputation. This cost may be considerable, as would the human cost to both the individual and their family – we believe that future studies in this area may benefit from the estimation of these costs.

We believe that our findings highlight the value of the contribution made by the clinical nurse consultant to the effectiveness of wound care in this remote region, particularly when there is an ongoing problem of high staff turn over. The loss of experienced clinical wound care staff has the potential to negatively effect the quality of wound care and creates the need to orient new staff to a relatively complex and specialised practice. During the course of our study, there was a significant turnover of staff at three of the four study sites; ideally, a study of this design should have maintained stable staffing at each site to reduce the potential for confounding the results. Unfortunately, clinical studies conducted in 'real' environments cannot always exert this level of control.

The problem of retaining nurses with wound care expertise in the Kimberley may be offset to a degree by using the AMWIS system and a remote consultant to provide continuity and expertise to the ongoing management of patients. A further benefit of the model used in our study may be the enhanced support and development of new staff being oriented to the wound care field. Ideally, a clinical nurse consultant or wound care nurse practitioner would be employed to provide consultation across the whole Kimberley region of WA.

On reviewing the frequency of remote wound consultation undertaken during the study, we believe that it may be possible to decrease the 2 weekly frequency and duration of

wound consultation that was used in this study. This assertion is based on observations of the increase in the knowledge and expertise of the local nurses that resulted from interaction with the consultant; however, further research would be required to quantify the actual changes in clinician wound management knowledge.

The determination of the degree to which wound management practices improved between the two groups as a consequence of the remote consultation was problematic. This was due to the variability in wound management between the four sites prior to the study commencing and, in particular, the variability between the two control sites during the study. It was therefore not possible to compare the control sites to the intervention sites on this parameter during the study. However, this is an important area that warrants further investigation in future studies.

An important issue that emerged in this study was the need for information technology (IT) support across all trial sites. Clinicians required support in the areas of data management and storage due to the large numbers of digital images stored as part of the AMWIS patient files. Initially, support was also required with establishing the AMWIS system on the various hospital networks and also during the initial trial of the encryption and e-mailing of data files for remote consultation. It was noted that IT support was also critical during interruptions to network services that at times made it difficult to use the AMWIS system.

Similarly, clinical leadership and support was of vital importance to this project. The leadership and support provided by the Directors of Nursing at the hospitals was critical to the successful establishment of both the AMWIS system and the process for remote consultation. Clinical leadership and commitment to the implementation of a telemedicine system such as AMWIS was seen as being of equal importance to that of technical support.

## Conclusion

This study presents early evidence for the clinical and cost effectiveness of remote expert wound consultation using a digital imaging telemedicine wound system. We believe that the study provides a potentially viable model for the delivery of more effective wound care in remote regions. Our results have demonstrated significant positive outcomes for patients with chronic lower limb ulcers as well as highlighting systemic factors that influence the successful introduction of telemedicine interventions in remote locations.

Whilst limited by incomplete data due to local practices and high staff turnover, we believe that this study provides a useful first step in demonstrating how digital imaging, combined with expert consultation, can support both wound care patients and clinicians, irrespective of their distance from major clinical centres.

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## Competing interests

None of the authors hold a financial interest in the AMWIS.

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